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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/635,315      | 08/06/2003  | Borje Rantala        | 2534-00074          | 8096             |

26753 7590 06/30/2005

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EXAMINER

MALLARI, PATRICIA C

ART UNIT PAPER NUMBER

3736

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |  |                                       |  |
|------------------------------|--|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/635,315   | <b>Applicant(s)</b><br>RANTALA, BORJE |  |
|                              | <b>Examiner</b><br>Patricia C. Mallari | <b>Art Unit</b><br>3736               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9,10,13,14 and 17 is/are rejected.
- 7) ☒ Claim(s) 3,4,7,8,11,12,15,16 and 18-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/6/03</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Objections***

Claims 5-8, 11, 12, and 14-16 are objected to because of the following informalities:

On lines 2-3 of claim 5, "characterized in that the method comprises the step of determining" should be replaced with "wherein a peripheral site plethysmographic sensor detects";

On line 4 of claim 5, "using peripheral site plethysmographic sensor" should be deleted;

On line 3 of claim 6, "measuring the peripheral site plethysmogram" should be replaced with "measuring a plethysmogram at the peripheral site";

On line 3 of claim 7, "the peripheral site plethysmogram" should be replaced with "a plethysmogram at the peripheral site";

On line 3 of claim 8, "heart beat to peripheral pulse beat" should be replaced with "heart to peripheral site";

On line 4 of claim 8, "the ECG" should be replaced with "an ECG";

On line 5 of claim 8, "QRS to ICG" should be replaced with "a QRS to impedance electrogram (ICG)";

On line 1 of claim 11, "claim 9" should be replaced with "claim 10", since claim 10 recites an oscillometric cuff and claim 9 does not;

On line 1 of claim 12, "claim 9" should be replaced with "claim 10", since claim 10 recites calibration of the blood pressure calculation and claim 9 does not.

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On line 1 of claim 14, "claim 11" should be replaced with "claim 13", since claim 13 recites that the peripheral site sensor is a plethysmographic sensor and claim 11 does not.

On line 1 of claim 15, "claim 9" should be replaced with "claim 13", since claim 13 recites that the peripheral site sensor is a plethysmographic sensor and claim 9 does not

On line 3 of claim 15, "plethysmogram" should be replaced with "plethysmograph" wherein a plethysmograph refers to the instrument itself while a plethysmogram refers to the record or tracing produced by the plethysmograph;

On line 3 of claim 16, "beat to beat" should be replaced with "pulse wave";

On line 4 of claim 16, "the ECG QSR-complex" should be replaced with "an ECG QRS-complex";

On line 6 of claim 16, "QRS to ICG" should be replaced with "a QRS to impedance cardiogram (ICG)";

On lines 3-4 of claim 17, "the peripheral site plethysmogram with an optical reflectance means" should be replaced with "a plethysmogram at the peripheral site with the plethysmographic sensor, wherein the plethysmographic sensor comprises an optical reflectance means";

On lines 3-4 of claim 18, "the peripheral site plethysmogram" should be replaced with "a plethysmogram at the peripheral site".

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 9, 10, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,648,828 to Friedman et al.

Friedman teaches a method for non-invasively measuring a blood pressure of a patient wherein an impedance cardiogram 12 determines a mechanical heart beat starting time point (col. 3, lines 53-57 of Friedman). A peripheral site sensor 26, 28 detects a heart beat pulse arrival time at a peripheral site of the patient (col. 3, lines 57-65 of Friedman). A first calculator 24 calculates the pulse wave transit time from the heart to the peripheral site by utilizing the mechanical starting point of the heart beat and the heart beat pulse arrival time (col. 3, line 66-col. 4, line 16 of Friedman). A second calculator 30 calculates the blood pressure from the pulse wave transit time (col. 4, lines 26-30 of Friedman).

Regarding claims 2 and 10 an oscillometric cuff 34 is used to calibrate the blood pressure calculation by measuring the blood pressure of the patient 14 (col. 4, line 30-col. 5, line 12 of Friedman).

Regarding claims 5 and 13, the peripheral site sensor 26, 28 is a plethysmographic sensor, wherein a pulse oximeter is a plethysmographic sensor (col.

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3, line 57-col. 4, line 5 of Friedman; also see col.7, lines 66-68 of US Patent No.

5,101,825 to Gravenstein et al. and col. 1, lines 47-49 of US Patent No. 5,782,756 to

Mannheimer for teaching of a pulse oximeter as a plethysmographic sensor.)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman, as applied to claims 1, 2, 5, 9, 10, and 13 above, and further in view of US Patent No. 5,490,523 to Isaacson et al. Friedman teaches using a pulse oximeter, but fails to describe the details of the oximeter. However, Isaacson describes a pulse oximeter for placement on the finger, the pulse oximeter being an optical reflectance means (fig. 10 of Isaacson). Therefore, it would have been obvious to one of ordinary skill in the art the time of invention to use the pulse oximeter of Isaacson as that of Friedman, since Friedman teaches using a pulse oximeter and Isaacson describes an appropriate such pulse oximeter.

The phrase "optical reflectance means" on line 4 of claim 6, line 3 of claim 14, and lines 3-4 of claim 17 fails to invoke 112, 6<sup>th</sup> paragraph. If the applicant wishes to have the claim limitation treated under 35 U.S.C. 112, 6<sup>th</sup> paragraph, the applicant must either amend the claim to include the phrase "means for" or "step for", or show that the claim limitation is written as a function to be performed and does not provide sufficient

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structure, material, or acts which would preclude application of 35 U.S.C. 112, 6<sup>th</sup> paragraph.

***Allowable Subject Matter***

Claims 3, 4, 7, 8, 11, 12, 15, 16, and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 3, 4, 11, and 12, the prior art of record fails to teach or fairly suggest a method or system for non-invasively measuring a blood pressure of a patient wherein the method or system includes calibration of the blood pressure calculation by oscillometric cuff measurement of the blood pressure of the patient and performing, successively the step of calibrating the blood pressure calculation by oscillometric cuff measurement, in combination with all of the other limitations of the claims.

Regarding claims 8 and 16, the prior art of record fails to teach or fairly suggest a method or system for measuring non-invasively a blood pressure of a patient wherein a pulse wave transit time from the heart to the peripheral site is calculated by utilizing the mechanical starting point of the heart beat and the heart beat pulse arrival time and by measuring the ECG QRS-complex and adding correction to the QRS-complex signal by averaging QRS to ICG waveform timing point, in combination with all of the other limitations of the claims.

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Regarding claims 7, 15, 18, and 20 the prior art of record fails to teach or fairly suggest a method or system for measuring non-invasively a blood pressure of a patient characterized in that a reflected wave component of the plethysmogram at the peripheral site is corrected in response to a change in plethysmogram amplitude, in combination with all of the other limitations.

Regarding claim 19, the prior art fails to teach or fairly suggest a system for non-invasive measurement of blood pressure wherein the calibration of the blood pressure calculation is improved incrementally on each cuff inflation cycle, in combination with all of the other limitations of the claim.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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